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|---|---|
| FLOOD, MICHELE C | |
| **ART UNIT** | **PAPER NUMBER** |
| 1654 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/655,935 | GAFNER ET AL. | |
| | Examiner | Art Unit | |
| | Michele Flood | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *8-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, Claims 1-2, in the reply filed on May 26, 2004 is acknowledged. The traversal is on the ground that while Howell et al. does arguably produce a product that is materially different from the product of claims 1 and 2, the process taught by Howell is not the process as claimed in the presently claimed invention. Applicant's argument is deemed persuasive; therefore, Group I has been rejoined with Group II.

**Claims 1-7 are under examination.**

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference characters not mentioned in the description: (1/). For instance, while the character "(1/1)" is used to reference the drawing, in [0008], Applicant merely refers to the drawing as "the sole accompanying drawing figure". Corrected drawing sheets, or amendment to the specification to add the reference character(s) in the description, are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be

notified and informed of any required corrective action in the next Office action.

The objection to the drawings will not be held in abeyance.

Perhaps, Applicant may overcome the rejection by referencing the drawing as Figure 1 in both the specification and in the drawing.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 and 7 are rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. An “extract” is necessarily a product-by-process because the composition of the “extract” is only defined by the process of its preparation. Such product-by-process claims are intended to define products which are otherwise difficult to define and/or distinguish from the prior art except by the process of making. Since any given biological source contains thousands of extractable compounds, each with it’s own particular extraction properties, the nature of the resulting “extract” will depend on the conditions of the extraction and the solvent used. For example, at what temperature is the extraction performed; is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, or an acid or base, or is it a squeezed extract? It is well

accepted in the natural products and herbal art, that extraction of a biological source with one of various distinct solvents has a profound impact on the final product with respect to the presence, amounts, and/or ratios of active ingredients obtained, and, thus, on the ability of the "extract" to provide the desired functional effect(s) claimed and/or disclosed. Since the "extract" itself is clearly essential to the instantly claimed invention, the step(s) by which the claimed "extract" is/are obtained is/are also clearly essential and, therefore, must be recited in the claims (i.e., as a product-by-process). Although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

The metes and bounds of Claims 1-3 are rendered uncertain because the percentage amounts of the ingredients are not set forth in terms of "by weight" of the total composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

With regard to Claim 6, line 1, although not rising to the level of uncertainty, it is apparent that a word was omitted from the claim language. Applicant may overcome the rejection by adding <u>said</u> before "solution" to place the claim in proper grammatical form.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Millspaugh (2, Millspaugh, CF, *Scutellaria Laterfolia*, American Medicinal Plants, pp 469-472, Dover Publication, New York) and Nishikawa et al. (U).

Applicant claims an extract of *Scutellaria lateriflora* L. having a flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I, ateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight. Applicant further claims the extract of claim 1 having a content of baicalin of at least 8-9% by weight.

On page 472, lines 1-4, Millspaugh teaches an evaporated, powdered tincture of *Scutellaria Laterfolia* made with 76 per cent alcohol, after dilution with water several times its bulk of water.

Nishikawa teaches an extract of *Scutellaria Laterfolia* comprising concentrations of flavonoids, such as acteoside (1), baicalin (2), wogonin 7-

glucuronide (3), baicalein (4), wogonin (5), skullcapflavone I (6), skullcapflavone II (7) and chrysin (8).

The Office notes that neither Millspaugh nor Nishikawa expressly teach that the reference extracts comprise each of the claim-designated flavonoids having the claim-designated percent amount by weight. However, the plant source material and the ingredients used in the making of the plant extracts taught by Millspaugh and Nishikawa are the same as instantly disclosed by Applicant. Thus, the claim-designated flavonoids having the claim-designated percent amount by weight are inherent to the extracts of *Scutellaria Laterfolia* taught by Millspaugh and Nishikawa.

The references anticipate the claimed subject matter.

***Claim Rejections - 35 USC § 102/35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Millspaugh (2, Millspaugh, CF, *Scutellaria Laterfolia*, American Medicinal Plants, pp 469-472, Dover Publication, New York) and Nishikawa et al. (U) in view of Sheu et al. (V), Wang et al. (8, Planta Med, 2002. 66(4): 535-537. Benziodizepine binding site-

Structure-activity relationships of flavonoids isolated from *Scutellaria baicalensis* root.), and Charaux et al. (W).

Applicant's claimed invention of Claims 1 and 2 was set forth above. Applicant claims a process for obtaining an extract of *Scutellaria lateriflora* L. rich in flavonoids, said process comprising: combining dried *Scutellaria lateriflora* L. plant material with a solvent to form a solution; and separating solid material from said solution after a predetermined period, whereby said extract has a content of flavonoids calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I, lateriflorin, baicalein, lateriflorein and wogonin, of at least 18% by weight. Applicant further claims the process of claim 3 wherein said solvent is boiling water; and, wherein said solvent is alcohol. Applicant further claims the process of claim 3 further comprising stirring the solution for a predetermined period; and, further comprising drying said extract.

The teachings of Millspaugh and Nishikawa are set forth immediately above.

The claims are drawn to an extract of *Scutellaria lateriflora* L. rich in claim-designated flavonoids in an amount of at least 18% by weight and having a content of baicalin of at least 8-9% be weight; and, a method of making thereof comprising claim-designated process steps, ingredients, process steps and experimental parameters.

The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition for the following reasons: Although Millspaugh and Nishikawa do not expressly

teach that the reference extracts have a content of flavonoidsd calculated as the sum of the claim-designated flavonoids in amount of at least 18% by weight, the Office deems that the extracts taught by Millspaugh and Nishikawa comprise the instantly claimed ingredients in the amount claimed by Applicant, since the plant source, the solvents, the process steps of extraction, and the experimental parameters for the process steps of extraction are the same as instantly claimed by Applicant; and, thus, the result effect for obtaining an extract *Scutellaria lateriflora* L. having flavonoids, calculated as the sum of baicalin, scutellarin, dihydrobaicalin, ikonnikoside I, lateriflorin, baicalein, lateriflorein and wogonin of at least 18% by weight; and, an extract having a content of baicalin of at least 8-9% by weight is considered inherent to the extracts and the process of making the plant extracts taught by Millspaugh and Nishikawa. Consequently, the claimed composition appears to be anticipated by the references.

In the alternative, even if the claimed composition is not identical to the referenced compositions with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced compositions are likely to inherently possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share, *e.g.,* the plant source, the solvents, the process steps of extraction, and the experimental parameters for the process steps of extraction are the same as disclosed by Applicant. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance,

it would have been obvious to one of ordinary skill in the art to obtain an extract of *Scutellaria lateriflora* L. having a content of flavonoids by using the instantly claimed ingredients, solvents, process steps and experimental parameters because to provide the instantly claimed inventions because at the time the invention was made it was known in the art of herbal extraction to use the instantly claimed process steps to obtain flavonoids from dried plant material of a species of *Scutellaria*, as evidenced by the teachings of Sheu, Wang and Charaux. Firstly, Sheu teaches a method for obtaining various flavonoids from the plant material of a *Scutellaria* plant, *i.e.,* baicalin (I), baicalein (II), wogonin (III) by extraction with water or water/methanol or ethanol. Sheu further teaches that the content of baicalin was dependent on the source of the plant material. For example, Sheu teaches, "The price of the crude drugs is proportional to the content of I but not related to II and III. The content of I, the most important biologically active component of Scutellariae root, in boiling water extracts of the wine-moistened samples is higher than that in extracts of untreated crude drugs by about 30%. However, it was lower when the samples were extracted with organic solvents. When the samples were soaked in water, the I content of the crude drugs decreased markedly (about half remained after 9 h soaking) but this had no effect on that of the processed samples. The processing of *Scutellariae* can effectively prevent the decomposition of I and increases its rate of extraction boiling water." Secondly, Wang teaches a method for obtaining various flavonoids from the plant material (roots) of a *Scutellaria* plant by extracting the plant material with an organic solvent and then with boiling water

three times, and concentrating the extract to dryness. In another instance, Wang teaches obtaining various flavonoids from the plant material (leaves) of a *Scutellaria* plant by extracting the plant material with water and then concentrating the extract. Wang further teaches that the water solution was chromatographed on a macroporous resin with various organic solvents, such as alcohol to determine the flavonoid content of the extract. Thirdly, Charaux teaches a method for the extraction of baicalin in leaves of Scutellaria by extracting fresh leaves with hot water and acidifying while hot. One of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to provide the instantly claimed extract employing the instantly claimed process steps for obtaining an extract of *Scutellaria lateriflora* L. rich in flavonoids because at the time the invention was made it was well known in the art that the instantly claimed source of plant material, process steps, solvents, and experimental parameters for the extraction of flavonoids from plant material of the claim-designated plant, such as the plant materials taught by Millspaugh and Nishikawa, were beneficial in the extraction of flavonoids. Thus, the instantly claimed extract and the method of making thereof would have been *prima facie* obvious and a matter of optimization to provide a result effect variable to one of ordinary skill in the art practicing the invention at the time the invention was given the references before him. Furthermore, references in conventional result-effective work conditions (*e.g.*, ingredients concentrations or order of process steps, length of process, *etc.*) does not support the patentability of claimed subject matter, unless there is clear and sufficient evidence indicating

such working condition(s) is/are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (see, e.g., MPEP 2144.05).

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note, "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER

MCF
August 2, 2004